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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,342	08/01/2003	Jonathan C. Makielski	960296.98989	4060

26734 7590 11/17/2006

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EXAMINER

PAK, MICHAEL D

ART UNIT PAPER NUMBER

1646

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/632,342	<b>Applicant(s)</b> MAKIELSKI ET AL.	
	<b>Examiner</b> Michael Pak	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 30-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Seq comparison attachment</u>          |

### **DETAILED ACTION**

1. Applicant's election with traverse of Group I, SEQ ID NO:7 in the reply filed on August 31, 2006 is acknowledged. The traversal is on the ground(s) that claims 45-47 should be grouped with Group I because the methods use the cells of group I. This is not found persuasive because claims 45-47 are grouped where the classification is separate. Applicants further argue that claim 48 should not be classified in both Group V and VI. Examiner agrees and will group claim 48 separately in a new Group VII drawn to method for determining a biological sample using polynucleotide probe or primers, classified in Class 435, subclass 6. Applicants further argue that separate restriction of sequences is not necessary because the specification on paragraph 29 describe the sequence relationships. However, each sequence must be searched in many databases separately and is a burdensome search.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-50 are pending. Claims 3-6, 8-9, 11-12, 14-15, 21-22, 24, 26, and 30-50 are withdrawn. Claims 1-2, 7, 10, 13, 16-20, 23, 25, and 27-29 are examined.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

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by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1-2, 7, 10, 13, 16-20, 23, 25, and 27-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Splawski et al. (US 6,342,357).

Splawski et al. disclose nucleic acid encoding SCN5A sodium channel (SEQ ID NO:4) which has an alteration at amino acid 552 of the claimed SEQ ID NO:8 encoded by the nucleic acid (columns 4-8; see attached sequence comparison). Splawski et al. disclose nucleic acid encoding SCN5A (SEQ ID NO:4) which has 99.5% amino acid sequence identity to the claimed SEQ ID NO:8 encoded by the nucleic acid (see sequence comparison attachment). Splawski et al. disclose vectors comprising the nucleic acid of above and cells comprising the vectors (columns 9-12).

4. No claims are allowed. Claims 17-18 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached on 8:00 - 2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Michael Pak  
Primary Patent Examiner  
Art Unit 1646  
12 October 2006

Seq Comparison Attachment

100	1513.5	14.4	1873	1	US-08-336-257A-7	Sequence 7, Appli	173	230.5	2.2	398	2	US-10-162-012-21	Sequence 21, Appli		
101	1512	14.4	2509	1	US-08-149-097D-35	Sequence 35, Appli	174	228.5	2.2	363	2	US-08-651-999A-4	Sequence 4, Appli		
102	1506.5	14.4	1912	2	US-09-495-714C-2	Sequence 2, Appli	175	228.5	2.2	363	2	US-09-385-752-4	Sequence 4, Appli		
103	1498.5	14.3	2546	2	US-09-949-016-9500	Sequence 9500, Ap	176	225.5	2.1	439	2	US-09-248-796A-20222	Sequence 20222, A		
104	1498.5	14.3	2546	2	US-09-949-016-9501	Sequence 9501, Ap	177	187.5	1.8	138	2	US-09-024-020B-12	Sequence 12, Appl		
105	1498	14.3	2265	1	US-08-149-097D-36	Sequence 36, Appl	178	187.5	1.8	138	2	US-09-425-043-12	Sequence 12, Appl		
106	1492	14.2	2265	1	US-08-149-097D-36	Sequence 36, Appl	179	183.5	1.7	54	1	US-08-401-512-56	Sequence 56, Appl		
107	1474.5	14.1	2336	2	US-09-269-446D-44	Sequence 44, Appl	180	183	1.7	968	2	US-08-651-999A-7	Sequence 7, Appli		
108	1474.5	14.1	2336	3	US-09-268-163-10	Sequence 10, Appl	181	183	1.7	968	2	US-09-385-752-7	Sequence 7, Appli		
109	1468.5	14.0	2237	3	US-09-033-026-8	Sequence 8, Appli	182	183	1.7	968	2	US-09-949-016-5914	Sequence 5914, Ap		
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111	1468.5	14.0	2339	3	US-09-268-163-6	Sequence 6, Appli	184	174	1.7	33	3	US-09-367-794-1	Sequence 1, Appli		
112	1468.5	14.0	2339	3	US-10-033-026-6	Sequence 6, Appli	185	173	1.6	696	2	US-08-906-865-4	Sequence 4, Appli		
113	1467.5	14.0	2237	1	US-08-455-543A-48	Sequence 48, Appl	186	173	1.6	705	2	US-09-129-668-4	Sequence 945, App		
114	1467.5	14.0	2237	1	US-08-223-305C-48	Sequence 48, Appl	187	172	1.6	705	2	US-09-538-092-945	Sequence 9700, Ap		
115	1467.5	14.0	2339	1	US-08-455-543A-47	Sequence 47, Appl	188	172	1.6	713	2	US-09-949-016-9700	Sequence 13, Appl		
116	1467.5	14.0	2339	1	US-08-223-305C-47	Sequence 47, Appl	189	171.5	1.6	532	2	US-10-162-012-13	Sequence 12, Appl		
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130	1257.5	12.0	309	2	US-08-605-284B-4	Sequence 25, Appl									
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132	1187.5	11.3	1666	2	US-09-949-016-8322	Sequence 16, Appl									
133	1184.5	11.3	310	2	US-08-605-284B-16	Sequence 2, Appli									
134	1092	10.4	211	3	US-07-745-206A-13	Sequence 13, Appl									
135	1050.5	10.0	1754	1	US-08-311-363-13	Sequence 19, Appl									
136	1050.5	10.0	1754	1	US-08-605-284B-19	Sequence 18, Appl									
137	973	9.3	307	2	US-08-605-284B-18	Sequence 6, Appli									
138	952	9.1	311	2	US-08-605-284B-17	Sequence 6, Appli									
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Sequence 21, Appli

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Sequence 12, Appl

Sequence 56, Appl

Sequence 7, Appli

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Sequence 5914, Ap

Sequence 10368, A

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Sequence 10, Appl

Sequence 13, Appl

Sequence 4, Appli

Sequence 53, Appli

Sequence 8, Appli

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US-08-401-512-56

US-08-651-999A-7

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US-10-162-012-8

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US-09-634-920-4

Sequence 4, Application US/09634920

Patent No. 6342357

GENERAL INFORMATION:

APPLICANT: Splawski, Igor

APPLICANT: Keating, Mark T.

TITLE OF INVENTION: ALTERATIONS IN THE LONG QT SYNDROME GENES KVLQT1 AND

TITLE OF INVENTION: SCNSA AND METHODS FOR DETECTING SMNE

FILE REFERENCE: 2323-155

CURRENT APPLICATION NUMBER: US/09/634,920

CURRENT FILING DATE: 2000-08-09

PRIOR APPLICATION NUMBER: 60/190,057

PRIOR FILING DATE: 2000-03-17

PRIOR APPLICATION NUMBER: 60/147,488

PRIOR FILING DATE: 1999-08-09

NUMBER OF SEQ ID NOS: 4

SOFTWARE: PatentIn Ver. 2.0

SEQ ID NO 4

TYPE: PRT

ORGANISM: Homo sapiens

US-09-634-920-4

Query Match

Best Local Similarity

Matches 2006;

Conservative

Score 10432.5;

DB 2;

Length 2016;

Pred. No. 0;

Mismatches

Indels

Gaps

1;

1

1

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121

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ALIGNMENTS

RESULT 1  
US-09-634-920-4  
; Sequence 4, Application US/09634920  
; Patent No. 6342357  
; GENERAL INFORMATION:  
; APPLICANT: Splawski, Igor  
; APPLICANT: Keating, Mark T.  
; TITLE OF INVENTION: SCENES IN THE LONG QT SYNDROME GENES KVLQT1 AND  
; FILE REFERENCE: 2323-155  
; CURRENT FILING DATE: 2000-08-09  
; PRIOR FILING DATE: 2000-03-17  
; PRIOR FILING DATE: 2000-03-17  
; PRIOR FILING DATE: 1999-08-09  
; NUMBER OF SEQ ID NOS: 4  
; SOFTWARE: PatentIn Ver. 2.0  
; SEQ ID NO 4  
; LENGTH: 2016  
; TYPE: PRT  
; ORGANISM: Homo sapiens  
US-09-634-920-4  
Query Match 99.5%; Score 10432.5; DB 2; Length 2016;  
Best Local Similarity 99.5%; Pred. No. 0;  
Matches 2006; Conservative 2; Mismatches 7; Indels 1; Gaps 1;  
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Seq 600mmesa A-TA-1000

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601 VSLGAGPEATSPGSHLLRPVLMHPDPTTTPSPRPGPOMLTQAPCVDGFEFGARQ 660  
661 RALSASVLTLSALRELSRHKPCPCWNLRAQYLIWECPLWMSIKOGVCLVWMDPTD 720  
661 RALSASVLTLSALRELSRHKPCPCWNLRAQYLIWECPLWMSIKOGVCLVWMDPTD 720  
721 LTITWCIWNTLFWALEHYNMTSEPEMLQVGNLVFTGIFTAEMTFKIALDPPYFQOG 780  
721 LTITWCIWNTLFWALEHYNMTSEPEMLQVGNLVFTGIFTAEMTFKIALDPPYFQOG 780  
781 WNIIFDSIIVLSLMEGLSRMSNLVLSRFLLRVFKLAKSWPTLTIKIIGNSVGALG 840  
781 WNIIFDSIIVLSLMEGLSRMSNLVLSRFLLRVFKLAKSWPTLTIKIIGNSVGALG 840  
841 NLTLVLAIIYFIPAVGQOLPGKNSYELRSDSGLLPRWMDPFAFLIIFRILCGEWI 900  
841 NLTLVLAIIYFIPAVGQOLPGKNSYELRSDSGLLPRWMDPFAFLIIFRILCGEWI 900  
901 ETWMDCEVSGQSLCLAVFLVWVIGNLVNLFLALLLSFSADNLTADEDEKEMNLQ 960  
901 ETWMDCEVSGQSLCLAVFLVWVIGNLVNLFLALLLSFSADNLTADEDEKEMNLQ 960  
961 LALARTQGLRPFVKTWDRCCGILLRORPQKPAALAAQGLPSCIATPYSPPETEKVP 1020  
961 LALARTQGLRPFVKTWDRCCGILLRORPQKPAALAAQGLPSCIATPYSPPETEKVP 1020  
1021 PTKRTRFEGEGOGGTGDPBPCVPIAVASDTDDQEDENSIGTRESK-QESQ 1079  
1021 PTKRTRFEGEGOGGTGDPBPCVPIAVASDTDDQEDENSIGTRESK-QESQ 1079  
1080 PVSOGGPEAPDSRTWSQVSATASSEASASQADWRQWKAQKABPQACGCTPDSCEGS 1139  
1080 PVSOGGPEAPDSRTWSQVSATASSEASASQADWRQWKAQKABPQACGCTPDSCEGS 1139  
1140 TADMTNTALLBQIPDLGQDVKDPCFTGCVRRCPCCAVDTTQAPGKWWRLKTCYH 1199  
1140 TADMTNTALLBQIPDLGQDVKDPCFTGCVRRCPCCAVDTTQAPGKWWRLKTCYH 1199  
1200 IVEHSWFETPIIFMILLSSGALAFEDIYLBERTIKVLEYADKMTYVYVLEMLKWA 1259  
1200 IVEHSWFETPIIFMILLSSGALAFEDIYLBERTIKVLEYADKMTYVYVLEMLKWA 1259  
1260 YGFKKYFTNWCWLDPLIVDSVLSVANTLGPAGMPKISLRTLRALRPLRALSPEGM 1320

## RESULT 2

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; Sequence 4, Application US/09840125

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; GENERAL INFORMATION:

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; APPLICANT: Keating, Mark T.

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